

IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF OKLAHOMA

JESSICA WELLS, individually and as	)	
next friend of J.W., a minor,	)	
	)	
Plaintiffs,	)	
	)	
vs.	)	Case Number CIV-12-973-C
	)	
ALLERGAN, INC.,	)	
	)	
Defendant.	)	

**ORDER**

Now before the Court is “Defendant Allergan, Inc.’s Motion to Exclude Expert Testimony of David A. Kessler, M.D.” (Dkt. No. 92). Defendant argues for the exclusion of Dr. Kessler’s testimony on the grounds that it offers impermissible legal conclusions, will not assist the trier of fact, is speculative, and is unfairly prejudicial. Defendant does not challenge Dr. Kessler’s qualification as an expert on FDA regulation of the pharmaceutical industry.\*

Federal Rule of Evidence 702 states:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion . . . if:

- (a) the expert’s scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data;

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\* Dr. Kessler earned a medical degree from Harvard Medical School and a law degree from the University of Chicago Law School, worked on food and drug issues for the United States Senate, served as Commissioner of the FDA under both President George H.W. Bush and President Clinton, served as the dean of two medical schools, taught drug regulation, consulted with private firms about drug regulation and FDA procedures, and has written and published numerous books and articles about the regulation of drugs and other public health topics.

(c) the testimony is the product of reliable principles and methods; and  
(d) the expert has reliably applied the principles and methods to the facts of the case.

Thus, to be admissible under Rule 702, the witness must be qualified as an expert, the testimony must be reliable, and the testimony must be relevant, meaning it would assist the trier of fact. See Bitler v. A.O. Smith Corp., 400 F.3d 1227, 1232 (10th Cir. 2004) (noting testimony must be both reliable and relevant); see also Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 591 (1993). Defendant's challenge centers on whether Dr. Kessler's testimony would be helpful to the jury.

Defendant first asserts that Dr. Kessler will "usurp the role of the Court" by "instruct[ing] the jury on a litany of legal issues." (Def.'s Br., Dkt. No. 92, at 6.) To the extent Allergan seeks to preclude Dr. Kessler from testifying about FDA regulatory requirements and procedures or offering his opinion as to Allergan's compliance therewith, the motion is DENIED. Defendant is correct that the Tenth Circuit prohibits experts from testifying so as "to direct the jury's understanding of the legal standards upon which their verdict must be based." Specht v. Jensen, 853 F.2d 805, 810 (10th Cir. 1988). However, in Specht, the court cautioned that it was drawing a narrow line and did not intend to "exclude all testimony regarding legal issues," as "a witness may refer to the law in expressing an opinion without that reference rendering the testimony inadmissible." Id. at 809. In this case, the Court disagrees with Allergan that Dr. Kessler's testimony about FDA regulations would "usurp" the role of the trial judge because this case is "not governed by federal regulations but by state law theories of negligence and strict liability." In re Fosamax Prods.

Liab. Litig., 645 F.Supp.2d 164, 191 n.16 (S.D.N.Y. 2009). Dr. Kessler’s testimony is admissible to assist the lay jury in “‘understand[ing] the complex regulatory framework that informs the standard of care in the pharmaceutical industry.’” In re Yasmin & YAZ (Drospirenone) Mktg., Sales Practices & Prods. Liab. Litig., Case No. 3:09-MD-02100-DRH, 2011 WL 6302287, at \*12 (S.D. Ill. Dec. 16, 2011) (quoting Foxamax, 645 F.Supp. at 191). Dr. Kessler may not testify as to the elements of a strict liability or negligence claim under Oklahoma law but may testify as to the law governing FDA regulations, Allergan’s compliance with those regulations, and the relationship between FDA regulations and state tort liability. See id. at \*11 (“The Supreme Court made clear in Wyeth that federal law does not prevent judges and juries in failure to warn cases from considering a drug companies [sic] compliance with FDA regulations.”). Cross-examination and competing expert testimony will ensure that the jury carefully weighs Dr. Kessler’s testimony. In addition, the Court will instruct the jury that the Court, not Dr. Kessler or any other witness, will inform the jury of the law applicable to this case.

Allergan also challenges Dr. Kessler’s testimony as having an improper basis. According to Defendant, Dr. Kessler’s expert opinion “amounts to mind-reading,” to the extent he “seeks to offer testimony about the knowledge, motivations, intent, state of mind, and purposes of Allergan, the FDA, and Dr. Wright.” (Def.’s Br. at 10-11.) The Court agrees with Defendant that “mind-reading is not the type of ‘specialized knowledge’ contemplated by Rule 702” and that Dr. Kessler cannot be permitted to speculate as to the intent or state of mind of Allergan, the FDA, or Dr. Wright. (Id.) However, although Dr.

Kessler cannot testify as to intent, Dr. Kessler can testify about facts from which the jury can infer intent. See, e.g., DePaepe v. Gen. Motors Corp., 141 F.3d 715, 720 (7th Cir. 1998) (holding an engineer could testify as an expert “that reducing the padding saved a particular amount of money . . . [and] that [the manufacturer’s] explanation for the decision was not sound (from which the jury might infer that money was the real reason); but he could not testify as an expert that [the manufacturer] had a particular motive”). Thus, Defendant’s motion with respect to state of mind testimony is GRANTED IN PART and DENIED IN PART. If Defendant feels that Dr. Kessler has departed from an analysis of the facts and entered the realm of speculation during his testimony, Defendant may object at trial.

Finally, Defendant contends that Dr. Kessler “improperly assumes the role of Plaintiffs’ advocate and invades the province of the jury” by “‘regurgitat[ing]’ the evidence through various factual narratives.” (Def.’s Br. at 13.) To the extent the facts relied upon by Dr. Kessler in forming his opinions are relevant and not cumulative, Dr. Kessler may include them in his testimony. However, Dr. Kessler may not “simply rehash[] otherwise admissible evidence about which he has no personal knowledge.” Highland Capital Mgmt., L.P. v. Schneider, 379 F.Supp.2d. 461, 468-69 (S.D.N.Y. 2005). An expert must do more than simply “constructing a factual narrative based upon record evidence” or “address[] ‘lay matters which a jury is capable of understanding and deciding without the expert’s help.’” Id. at 469 (quoting In re Rezulin Products Liab. Litig., 309 F.Supp.2d 531 (S.D. N.Y. 2004)). Thus, Defendant’s Motion is GRANTED IN PART and DENIED IN PART. Defendant may

object at trial if Dr. Kessler appears to be simply regurgitating facts, rather than using relevant facts as context for his expert opinions.

Accordingly, for the reasons and to the extent stated above, “Defendant Allergan, Inc.’s Motion to Exclude Expert Testimony of David A. Kessler, M.D” (Dkt. No. 92) is hereby GRANTED IN PART and DENIED IN PART.

IT IS SO ORDERED this 4th day of February, 2013.



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ROBIN J. CAUTHRON  
United States District Judge